

68451-1

4/3/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Micah T. Reynolds, Agent
Intervet, Inc.
c/o Technology Sciences Group, Inc
1150 18th Street NW, Suite 1000
Washington, DC 20036

APR - 3 2014

Subject: Notification – Removing One Alternate Brand Name, Adding Numerous Alternate Brand Names, and Adding Marketing Claims
EPA Registration Number: 68451-1
Product Name: Deltamethrin 4% Collar
Submission Date: March 27, 2014
Decision Number: 489463

Dear Mr. Reynolds:

The Agency is in receipt of your Application for Pesticide Notification dated March 27, 2014 for 68451-1. The Registration Division has conducted a review of this request for its applicability under the Pesticide Registration Notice 98-10, and finds that the action requested does fall within the scope of the PRN.

Pesticide Registration Notices are provided as guidance; they are not considered regulation by the Agency, and that the Registration Division reserves the right to make the determination of acceptability. **The Registration Division has determined that this action is acceptable**, and our records have been updated accordingly.

If you have any questions, please contact me via email at "walsh.michael@epa.gov" or by telephone at 703-308-2972.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Walsh".

Michael Walsh
Acting Product Manager (13)
Insecticide Branch
Registration Division (7505P)
Office of Pesticide Programs

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Mike Walsh	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# 13	
5. Name And Address Of Applicant (Include ZIP Code) Intervet, Inc. 556 Morris Avenue Summit, New Jersey 07901 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain Below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Label Notification to add Alternate Brand Names and Optional Marketing Claims.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please confirm receipt with Micah Reynolds: mreynolds@tsgusa.com, via phone (202) 828-8967, or via fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" No. per Unit Packaging wgt. Container	If "Yes" No. per Unit Packaging wgt. Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	
6. Manner in Which Label is Affixed to Product		5. Location of Label Directions	
<input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product <input type="checkbox"/> Other _____	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Intervet, Inc.	
4. Typed Name Micah T. Reynolds	5. Date March 27, 2014	

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DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

- | | |
|--|--|
| SCALIBOR® Flea and Tick Collar for Dogs | SCALIBOR® Collar with Deltamethrin |
| SCALIBOR® Flea & Tick Collar for Dogs | SCALIBOR® Collar with 4% Deltamethrin |
| SCALIBOR® Dog Collar for Flea and Tick Control | SCALIBOR® Long Lasting Collar for Dogs |
| SCALIBOR® Dog Collar for Flea & Tick Control | SCALIBOR® Deltamethrin Collar for Dogs |
| SCALIBOR® Collar for Dogs | SCALIBOR® Protector Band for Dogs |
| SCALIBOR® 6-Month Collar for Dogs | SCALIBOR® Tick and Flea Collar for Dogs |
| SCALIBOR® 6-Month Flea and Tick Collar for Dogs | SCALIBOR® 6-Month Flea & Tick Collar for Dogs |
| SCALIBOR® Tick & Flea Collar for Dogs | SCALIBOR® Dog Collar for Tick & Flea Control |
| SCALIBOR® Six Month Collar for Dogs | SCALIBOR® Dog Collar for Tick and Flea Control |
| SCALIBOR® Six Month Flea and Tick Collar for Dogs | SCALIBOR® 6-Month Tick & Flea Collar for Dogs |
| SCALIBOR® Six Month Flea & Tick Collar for Dogs | BandGuard® Collar with Deltamethrin |
| SCALIBOR® Six Month Tick & Flea Collar for Dogs | BandGuard® Collar with 4% Deltamethrin |
| SCALIBOR® Six Month Tick and Flea Collar for Dogs | BandGuard® Long Lasting Collar for Dogs |
| SCALIBOR® 6-Month Tick and Flea Collar for Dogs | BandGuard® Collar for Dogs |
| BandGuard® Flea and Tick Collar for Dogs | BandGuard® Protector Band for Dogs |
| BandGuard® Flea & Tick Collar for Dogs | BandGuard® 6-Month Flea and Tick Collar for Dogs |
| BandGuard® Dog Collar for Flea and Tick Control | BandGuard® Tick & Flea Collar for Dogs |
| BandGuard® Dog Collar for Flea & Tick Control | BandGuard® Dog Collar for Tick & Flea Control |
| BandGuard® Deltamethrin Collar for Dogs | BandGuard® Dog Collar for Tick and Flea Control |
| BandGuard® 6-Month Collar for Dogs | BandGuard® 6-Month Tick & Flea Collar for Dogs |
| BandGuard® Tick and Flea Collar for Dogs | |
| BandGuard® 6-Month Flea & Tick Collar for Dogs | |
| BandGuard® Six Month Collar for Dogs | |
| BandGuard® Six Month Flea and Tick Collar for Dogs | |
| BandGuard® Six Month Flea & Tick Collar for Dogs | |
| BandGuard® Six Month Tick & Flea Collar for Dogs | |
| BandGuard® Six Month Tick and Flea Collar for Dogs | |
| BandGuard® 6-Month Tick and Flea Collar for Dogs | |

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar
See Insert or Side Panel for additional Precautionary Statements
See Back for additional Precautionary Statements

Adjustable – One Size Fits All

NOTIFICATION
04032014

Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 2 of 6
revision date: 4-3-2014

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Intervet Inc (d/b/a Merck Animal Health)
Summit, NJ 07901

Product of France

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

[Product Name] provides full season, up to 6 months protection against fleas and ticks

**PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals**

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
For incidents involving HUMANS , call 1-800-680-9206 For incidents involving ANIMALS , call 1-800-224-5318 EST between the hours of xxx and xxx. Evenings and week-ends call 800-345-4735 Have the product container or label with you when calling a poison control center or doctor, or going for treatment	

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Wipe the collar with a damp cloth prior to application. Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. [Product Name] may be used in addition to a lead or constraint collar. Use only one [Product Name] at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France

OPTIONAL/ALTERNATE LABEL TEXT

[Product Name], containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (*Ctenocephalides sp.*) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill ticks for up to 6 months including: Lone Star tick (*Amblyomma americanum*), Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills fleas

Kills ticks (including deer ticks which may transmit *Lyme disease*)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lyme disease and Southern Tick-Associated Rash Illness (STARI))

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name) kills fleas and may reduce the incidence of FAD

OPTIONAL/ALTERNATE LABEL TEXT (cont'd)

Deltamethrin 4% Collar
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(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection
Not affected by water

Water resistant

Repels mosquitoes for up to six months.

Reduces mosquito bites for up to six months.

Reduces blood feeding by mosquitoes for up to six months.

Protects against mosquito bites for up to six months.

